REMARKS

Amendments to the Specification

Paragraph [0042], on pages 33-34 of the specification, has been amended to correct a typographical error. The incorrect accession numbers, FERM ABP-___, have been amended to the correct accession numbers, FERM BP-_____. Support for the amendments is found, *e.g.*, in the translations of deposit receipts for two of the hybridomas that are presently claimed (claim 105), which are attached hereto.

The claims

Claims 103 and 105 are amended to address concerns raised by the Examiner. Claim 104 recites an embodiment of the invention in which the two types of monoclonal antibodies are used to detect the denatured ovalbumin allergens by immunochromatography, rather than by sandwich ELISA as is recited in claim 103. New claim 112 is added.

Support for these amendments, as well as new claim 112, is found in the specification, *e.g.*, at paragraph [0026] as originally filed (pages 18-19), which states: "As the above anti-ovalbumin monoclonal antibodies, anti-ovalbumin monoclonal antibodies recognizing a native ovalbumin and/or a reduced carboxymethylated ovalbumin are preferable. Specifically, the anti-ovalbumin monoclonal antibody PNOA1 produced by hybridoma (FERM ABP-10265), the anti-ovalbumin monoclonal antibody PNOA2 produced by hybridoma (FERM ABP-10266), the anti ovalbumin monoclonal antibody PDOA1 produced by hybridoma (FERM ABP-10275), the anti ovalbumin monoclonal antibody PDOA2 produced by hybridoma (FERM ABP-10276) etc. can be preferably exemplified. Further, by using the combination of anti-denatured ovalbumin monoclonal antibodies such as PDOA1 and PDOA2, sandwich ELISA or immunochromatography can be performed more advantageously";

and at paragraph [0035] (pages 27-28), which states: "a double-antibody sandwich method using a labeled anti-food allergen MAb (secondary antibody) recognizing an epitope different from an anti-food allergen MAb bound to an insolubilized carrier" and "an immunochromatology method wherein an anti-food allergic protein MAb binding to a food allergen is fixed in advance on the test strip where an antigen-antibody complex, in which an anti-food allergen MAb labeled with such as gold colloid and a food allergenic protein are

bound, moves by a capillary phenomenon etc., and a qualitative analyze is performed according to the presence or absence of a colored line appearing by trapping the antigen-antibody complex."

Rejection of claims 103-105 under USC 112, second paragraph, and USC 101

These claims are amended to set forth active steps. The claim amendments clarify that a method of the present invention can detect denatured albumen allergens, wherein the allergens are detected by sandwich ELISA or immunochromatography, using two types of antibodies recognizing a reduced carboxymethylated ovalbumin, and each recognizing a different epitope.

It is respectfully requested that the rejections be withdrawn.

Rejection of claims 103 to 105 under USC 102, over Narita *et al.*

The above amendments clarify that the method is for detecting ovalbumin. By contrast, Narita *et al.* discloses a method for detecting ovomucoid. Furthermore, Narita *et al.* uses antibodies that recognize heat-denatured ovomucoid, while the method of the present claims uses antibodies that recognize a reduced carboxymethylated ovalbumin.

To anticipate a claim, a reference must teach each and every limitation of the claim. That is clearly not the case here.

Applicants respectfully request that the rejection be withdrawn.

Rejection of claims 103 to 105 under USC 102, over Kilshaw *et al.*

The study in Kilshaw *et al.* is designed to reveal information about molecular features of allergic food proteins after absorption, and ELISA techniques are used to determine the specificity of the antibodies for egg ovalbumin in normal human serum. The authors report that serum from 90% of healthy adult human donors contained IgG antibodies to ovalbumin, and that in nearly all cases the antibodies were specific predominantly for the native molecule and could not be absorbed with denatured ovalbumin or peptides prepared from it by cleavage with cyanogen bromide or trypsin (see, *e.g.*, the Summary).

Kilshaw *et al.* reach the conclusion that although ovalbumin is ingested largely in a denatured form, the human serum antibody response is stimulated mainly by native molecules. Therefore, although Kilshaw *et al.* describes antibodies recognizing different epitopes and their

specificity, it does *not* describe the detection of denatured albumen allergen in food. In addition, Kilshaw *et al.* does not teach or suggest that denatured albumen allergen in food can be detected in a highly accurate way by performing sandwich ELISA (double antibody procedure) or immuno-chromatography using the combination of the presently claimed antibodies.

By contrast, the method of the present invention is a method for detecting *denatured* albumen allergens, wherein the allergens are detected by sandwich ELISA or immuno-chromatography, using two types of antibodies recognizing a reduced carboxymethylated ovalbumin, each recognizing a different epitope.

For at least the preceding reasons, applicants contend that Kilshaw *et al.* does not teach each and every element of the presently claimed method for detecting denatured albumen allergens, and thus does not anticipate the present claims. Applicants respectfully request that the rejection be withdrawn.

In view of the preceding amendments and arguments, it is believed that the application is in condition for allowance, which action is respectfully requested.

Should any additional fee be deemed due, please charge such fee to our Deposit Account No.22-0261, referencing docket number 31671-235624 and advise us accordingly.

Dated: **September 16, 2009**

Respectfully submitted,

By Nancy Axelrod

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「特許手続上の微生物の寄託等の国際的承認に関するブダペスト条約」

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

下記国際寄託当局によって規則7.1に従い発行する。

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

原寄託についての受託証

氏名（名称）

寄託者　　プリマハム株式会社
代表取締役社長　貴納　順二　殿

あて名　〒 140-8529
東京都品川区東大井3-17-4

I. 微生物の表示	
(寄託者が付した識別のための表示) PDOA1	(受託番号) FERM BP-10275

II. 科学的性質及び分類学上の位置

I欄の微生物には、次の事項を記載した文章が添付されていた。

☑ 科学的性質
☑ 分類学上の位置

III. 原寄託申請の受託

本国際寄託当局は、 平成 17 年 2 月 24 日に受領したI欄の微生物を受託する。

IV. 移管申請の受託

本国際寄託当局は、　年 月 日(国内受託日)に受託したI欄の微生物を受託する。

(　年 月 日に寄託されたFERM P-　より移管)

V. 国際寄託当局

独立行政法人産業技術総合研究所　特許生物寄託センター

名称　International Patent Organism Depositary
National Institute of Advanced Industrial Science and Technology

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Ibaraki-ken 305-8566 Japan

平成 17 年 (05) 2 月 24 日

Form 8 (related to Section 7, Paragraph 1)

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROOGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

RECEIPT IN THE CASE OF ORIGINAL DEPOSIT (translation)

TO DEPOSITOR:

Name: Prima Meat Packers, Ltd.

Representative: Junji KINOU, President

Address: 17-4, Higashi-ohi 3-chome, Shinagawa-ku, Tokyo 140-8529

I. IDENTIFICATION OF MICROOGANISM	
Identification Reference Given by the Depositor: PDOA1	Accession Number: FERM BP – 10275
II. SCIENTIFIC DESCRIPTION AND PROPOSED TAXONOMIC POSITION	
The microorganism identified under the above section I was accompanied by a document stating the following item(s). ■ Scientific Property ■ Taxonomic Position	
III. RECEIPT AND ACCEPTANCE OF REQUEST FOR ORIGINAL DEPOSIT	
This International Depositary Authority accepts the microorganism identified under the above section I, which was received on February 24, 2005.	
IV. RECEIPT OF REQUEST FOR TRANSFER	
This International Depositary Authority received the microorganism under the above section I on (date of national deposit). (transfer from FERM P – deposited on)	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology Representative: Dr. Masakazu YAMAOKA, Director Address: AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan Date: February 24, 2005	

書式8（第7条第1項関係）

「特許手続上の微生物の寄託等の国際的承認に関するブダペスト条約」

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原寄託についての受託証

氏名（名称）

寄託者　プリマハム株式会社
代表取締役社長　貴納 順二　殿

あて名　〒 140-8529
東京都品川区東大井3-17-4

I. 微生物の表示	
（寄託者が付した識別のための表示） PDOA2	（受託番号） FERM BP-10276

II. 科学的性質及び分類学上の位置

I欄の微生物には、次の事項を記載した文章が添付されていた。

☑ 科学的性質
☑ 分類学上の位置

III. 原寄託申請の受託

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IV. 移管申請の受託

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（　年 月 日に寄託されたFERM P-　より移管）

V. 国際寄託当局

独立行政法人産業技術総合研究所 特許生物寄託センター

名称　International Patent Organism Depositary
National Institute of Advanced Industrial Science and Technology

センター長　山岡 [illegible]

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Ibaraki-ken 305-8566 Japan

平成 17 年 (05) 2 月 24 日

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Representative: Junji KINOU, President

Address: 17-4, Higashi-ohi 3-chome, Shinagawa-ku, Tokyo 140-8529

I. IDENTIFICATION OF MICROOGANISM	
Identification Reference Given by the Depositor: PDOA2	Accession Number: FERM BP – 10276
II. SCIENTIFIC DESCRIPTION AND PROPOSED TAXONOMIC POSITION	
The microorganism identified under the above section I was accompanied by a document stating the following item(s). ■ Scientific Property ■ Taxonomic Position	
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Name: International Patent Organism Depositary National Institute of Advanced Industrial Science and Technology Representative: Dr. Masakazu YAMAOKA, Director Address: AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan Date: February 24, 2005	